Biotech Daily

Friday May 9, 2025

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Dimerix

By TIM BOREHAM

ASX code: DXB

Share price: 66 cents

Shares on issue: 560,041,699

Market cap: $369.6 million

Chief executive officer: Dr Nina Webster

Board: Mark Diamond (chair), Dr Webster, Hugh Alsop, Dr Sonia Poli, Clinton Snow

Financials (March 2025 quarter): customer receipts $3.5 million, cash outflows $4.3 million, cash of circa $70 million (after $52.1 million payments from Amicus and Fuso)

Identifiable major holders: Peter Meurs 13.6%, Precision Opportunities Fund 1.8%, Bavaria Bay Pty Ltd (Perth high net worth individuals) 1.3%

As a former bus driver, Dimerix CEO Dr Nina Webster knows that the drug development journey is just as important as the destination when it comes to delivering value to shareholders.

The therapeutic trip can be painfully long, especially when investors are in the back street screaming: 'are we there yet'?

The developer of a drug for a rare kidney disease, Dimerix is out of the depot and down the road. But with the results of its phase III trial not due for some years, the company needs to navigate a few more twists and turns.

At least it's keeping the kids in the back - er, shareholders - entertained with some scenic road stops and ice cream along the way.

Last week, Dimerix shares rocketed after the company announced its fourth - and largest - geographic partnership, with the Nasdaq-listed rare diseases house Amicus Therapeutics.

The deal delivers $US30 million ($A48 million) upfront to Dimerix, with the potential for up to $US520 million of success-based payments. That's a lot of Choc Wedges.

Dimerix CEO Dr Nina Webster dubs the deal as "likely to be one of the biggest in the history of Australian biotech". Who are we to argue?

"We are absolutely thrilled to be partnering with Amicus," she adds.

The four deals have delivered $66.5 million in upfront cash, with $1.4 billion of potential milestones - payable mainly when the company reaches its destination of US Food and Drug Administration (FDA) approval (see 'finances and performance').

But what's the point of the journey?

Dimerix is developing its lead compound, DMX-200, for the rare and regressive kidney disease focal segmental glomerulo-sclerosis (FSGS).

FSGS attacks the kidney's filtering units - glomeruli - causing irreversible scarring and permanent kidney damage. Kidney failure typically happens within five years of diagnosis, with 60 percent of patients receiving a transplant experiencing recurring FSGS.

With no other disease-specific treatment available, the FDA has accorded the condition orphan drug designation. This confers benefits such as marketing exclusivity, higher prices and other regulatory leg-ups.

Currently, FSGS is treated with blood pressure medications known as angiotensin receptor blockers.

A bit of history

Dimerix was founded in 2004 by Dr James Williams and former Macquarie Group adviser Liddy McCall, based on technology developed at the University of Western Australia.

Dimerix Bioscience was acquired in July 2015 by the ASX-listed Sun Biomedical, which was developing saliva-based drug tests. The company changed its name to Dimerix Limited in November 2015.

Patent lawyer and scientist Kathy Harrison was appointed inaugural CEO in August 2017, having been the company's sole employee when she joined in 2014. A year later she was replaced by Dr Webster.

Also, a patent lawyer – as well as a former bus driver - Dr Webster held senior positions at drug companies including Wyeth Pharmaceuticals (now Pfizer), Acrux and Immuron.

Amic-able deal

Dr Webster says the $US2.2 billion Amicus is an ideal partner because it already has two rare disease medicines and considerable commercial and regulatory experience.

"Collectively this puts us in a far stronger position to bring our exciting drug candidate to patients with limited treatment options."

Here's the nitty-gritty: Amicus pays an upfront US$30 million ($A48 million) to Dimerix, with the potential for up to US$520 million of success-based payments.

These milestones consist of $US410 million of sales milestones, $US75 million on regulatory approval and $US35 million on first sales. Dimerix is also entitled to tiered royalties on sales, in the "low tens to low twenties" percentage range.

"The royalties we have achieved are very good for a deal of this structure and fit very much with the industry standard," Dr Webster says.

Amicus becomes responsible for the FDA approval process and selling the drug, while Dimerix bears the ongoing phase III trial costs. Dr Webster says the Amicus deal had been negotiated in earnest since last November, in a competitive tender process.

Past - and future - deals

Unveiled in October 2023, Dimerix signed the European, Canadian, Australia and New Zealand rights to the London-based Advanz Pharma. This deal delivered $10.8 million upfront and potential milestones of $219 million.

In May last year, the company struck a deal for Iraq and the Gulf Countries with the World Health Organisation.

In January this year, Dimerix then signed on the dotted line with Japanese company Fuso, which delivered another $7.2 million upfront and $100 million of potential milestones.

Investor attention now turns to likely follow-on deals in the major territories still up for grabs. These include China, Latin America and South Korea.

Dr Webster cites "significant interest" from potential partners, but "deals get done when they get done".

Action stations

Dimerix's centrepiece is its ongoing phase III trial, dubbed Action 3, which combines DMX-200 with the standard-of care blood pressure drugs.

The trial aims for 286 patients across multiple sites, with 185 already randomized and dosed. The study is blinded and placebo-controlled, with the patients medicated for two years, at 70 sites in 11 countries.

The primary endpoint is the reduction in the amount of protein seeping from blood in the urine - proteinuria - a telltale sign of kidney disease. This is a similar endpoint to the company's phase II trial.

In 2020, the company reported the phase II showed a circa 17 percent proteinuria reduction relative to placebo, on top of a 15 to 20 percent benefit from the standard-of-care drug (as measured by published data).

In a March 2024 interim phase III analysis of the first 72 patients, the company reported DMX-200 performing better than placebo in reducing proteinuria.

Because the trial was blinded, this finding stemmed from statistical modelling.

"This suggests DMX-200 may achieve a statistically significant and clinically meaningful result at the end of the study," Dr Webster says. "The results are very encouraging, especially for FSGS patients who currently have very limited treatment options."

The company adds that 42 patients have completed the two-year treatment and rolled on to the open-label extension trial.

What's next?

Dimerix expects Action 3 enrolment to complete by the end of 2025. Then there's a two-year wait for all of them to finish the treatment and then a few months of analysis before a final read-out.

Equating progress to a Melbourne-to-Sydney slog up the Hume Highway, we're at Gundagai. But there are diversions along the Action 3 highway far more interesting than the dog on the tucker box.

Sometime before the end of calendar 2025, Dimerix should produce a second interim analysis, which could pave the way for an FDA accelerated approval application.

This means that while the company would have to complete the trial, it would be able to sell the drug before then.

Last week, the FDA told the company it would accept proteinuria as a so-called 'surrogate endpoint' for the trial. The alternative is to wait for the incidence of kidney end failure, which could take years.

Dimerix can use the proportion of patients either achieving a defined proteinuria reduction relative to placebo, or the percentage change in proteinuria from baseline.

In any event, the company has been keeping data on both proteinuria trends and estimated glomerular filtration rate (EGFR), which measures the loss of kidney function more directly.

“Proteinuria is far easier to measure because it has far fewer variabilities, so you will get better statistical powering with it,” Dr Webster says.

Meanwhile, Dimerix is liaising with a third-party working group called Parasol, which will advise on an “appropriate endpoint for accelerated approval in FSGS”, which should take three to six months.

Because the next analysis is also blinded, the company needs to discuss the parameters for unblinding with the FDA.

Finances and performance:

At the end of March, Dimerix had cash of $17.5 million and this week banked the $48 million Amicus upfront payment. The company expects the $4.1 million from the Fuso agreement to lob this quarter.

So, let’s say Dimerix has a smidge under $70 million of cash.

There are more riches on the way, with options worth up to $6.2 million due to expire in June 2025. The options are exercisable at 15.3 cents, so there’s a handy 360 percent gain on the table. Any investor who forgets to convert will be kicking themselves.

Dr Webster says Dimerix has spent around $60 million on the Action 3 trial to date. But having broken the back of the recruitment stage - the most expensive stanza - outgoings should moderate.

Dr Webster says the company is well-funded to pursue its development pipeline and other potential opportunities (see below).

On potential drug pricing, there’s no directly comparable FSGS therapy.

Dr Webster says rare disease drugs in the US typically sell for $US120,000 to $US500,000 per patient per year.

Over the last 12 months Dimerix shares have traded between 31 cents in late December last year and 76 cents last Friday.

The shares could be picked up for a mere six cents in late 2023. Interestingly, in September 2020 the stock traded at around 74 cents - not far off-peak levels - well before the four company-transforming partnerships.

Other diseases?

While the US deal involves all DMX-200 indications, the company is free to ponder other therapies.

Dimerix has another pre-clinical drug candidate called DMX-700, which targets major lung ailments including chronic obstructive pulmonary disease (COPD). DMX700 works by blocking the interleukin-8 (IL-8) receptor, which is expressed at elevated levels in sick patients. This in turn causes lung tissue damage.

Cystic fibrosis has been mentioned in dispatches, as well as diabetic kidney disease (DKD). The DKD market has heavy competition and would require much bigger trials, while the advent of anti-obesity GLP-1 drugs may ameliorate the incidence of the disease.

Dr Boreham's diagnosis:

The spectre of eye drug developer Opthea's recent two-phase III trial results cast a dark shadow over the sector. In road trip terms, Opthea followed Siri (the FDA's guidance) to the word but still ended up a dead-end.

So why should Dimerix holders be reassured?

Apart from the company's positive interim data readout, Dr Webster says the four global partners all underwent extensive due diligence.

"Dimerix has good validation of the asset, both technically and commercially," she says. "We have already demonstrated a strong safety profile and have collected encouraging efficacy data, across both the phase II trial and the first unblinded clinical analysis of the phase III trial."

FSGS is a worthwhile journey for the company to make, with the potential market estimated at $US6 billion a year by 2032, across eight key geographies (including $US2 billion in the US).

That said, Dimerix is wise in organizing some 'side trips' by way of its secondary programs as the risks with DMX-200 - which combines two compounds - always will remain.

As Opthea has attested, driving miles and miles only to find a flea-ridden Bed and Breakfast is no one's idea of fun.

Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Being old fashioned, his guiding star is Melways, not Siri and Gen Y-ers will need to Google this reference.